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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,148	02/01/2002	Marie-Cecile Van de Lavoie	271/123	4804
34313	7590	03/31/2004		
ORRICK, HERRINGTON & SUTCLIFFE, LLP 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558				
			EXAMINER KAUSHAL, SUMESH	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	Application No.	Applicant(s)	
	10/067,148	VAN DE LAVOIR ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

All participants (applicant, applicant's representative, PTO personnel):

(1) Sumesh Kaushal Ph.D.

(3) Robert Etches.

(2) Kurt L. Mulville.

(4) Robert M. Kay.

Date of Interview: 24 March 2004.

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: the attachment  
2 Power Point presentation,

Claim(s) discussed: 21,26-30 and 41-52.

Identification of prior art discussed: Pain et al.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See below.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

*The applicant is considering filing a declaration to provide evidence that chicken embryonic stem cells when transfected in a culture more than 60 days maintain their ability to contribute to all the major tissues of a hatched chimeric chicken*

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

*Sumesh Kaushal*  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



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**FAX TRANSMISSION**

**DATE** March 22, 2004

**NO. OF PAGES**  
**(INCLUDING COVER SHEET)** 8

**FROM**

*name* Kurt T. Mulville  
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*fax* 949/567-6710

**TO**

<i>name</i>	<i>company/firm</i>	<i>tel</i>	<i>fax</i>
Ex. Sumesh Kaushal	U.S. Patent & Trademark Office		571/273-0769

**RE** Amendment and Response

**MESSAGE**

C-M-A 700603.2 KTM/sjh

**IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL SALLY HARTWELL AT  
949/852-7736 AS SOON AS POSSIBLE.**

*notice to recipient*

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DOCSOC1:148965.1

**INTERVIEW AGENDA - Examiner Kaushal  
Kurt T. Mulville**

10/067,148 and 10/216,098

**Discuss Technology Background**

- I. Avian Transgenesis. Types of Approaches**
  - A. Nuclear Transfer – past efforts
  - B. Retroviral – specifics of technology and history
  - C. Current State of the Art
  - D. New citations in IDS
- II. Origen: ES Cells and Transgenes**
  - A. Long-Term Cell Culture
  - B. Chimeras Harboring ES Cell Progeny With Genetic Modifications (transgene)
  - C. Tissue Specific Expression
- III. Pending Applications**
  - A. ES Cell—10/067,148
  - B. Tissue Specific Expression—10/216,098
  - C. Claims to Long-Term ES-Cell Derived Chickens with Transgene
  - D. Claims to Tissue Specific Expression

FREE  
FOR  
VT/

Patent  
700603.3  
(former L&L 271/123)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

**Marie-Cecile van de Lavoir, et al.**

**Serial No.: 10/067,148**

**Filed: February 1, 2002**

**For: CHIMERIC BIRD FROM EMBRYONIC STEM CELLS**

**Group Art Unit: 1636**

**Examiner: Sumesh Kaushal**

## AMENDMENT AND RESPONSE

Commissioner for Patents  
Washington, DC 20231

**Sir:**

**Please amend the above application as follows.**

04/02/2004 KTURNER 00000001 150665 10067148

01 FC:2251 55.00 DA

collaborated to interview Symmes

## CERTIFICATE OF TRANSMISSION

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted via facsimile (571/273-0769) on the date shown below to Examiner Surmesh Kaushal, Commissioner for Patents, P.O. Box 1450, Alexandria 22313-1450.

**March 22, 2004**  
**Date of Transmission**

*Karen Johnson*  
Karen Johnson

DOCSOC1:141969-1  
700603-3 KLM

Patent  
700603.3  
(former L&L 271/123)

Amendments to the Specification

Page 1, before "FIELD OF THE INVENTION," please insert the following paragraph:

This invention was made in part from government support under Grant No. R44 HD 39583  
National Institute of Health (NIH) of the United States. The U.S. Government may have certain  
rights in this invention.

*Attachment to interview memo*

Patent  
700603.3  
(former L&L 271/123)

## Amendments to the Claims

Please cancel claims 1-20, 22-25, 31-40, and 49-50 without prejudice.

Please amend claims 21, 26-30, 41-48 as follows:

1-20 (Cancelled)

21. (Currently Amended) A hatched chimeric chicken comprised of progeny of embryonic stem cells having a genome comprising a stably integrated transgene and sustained in culture for more than 60 days, wherein a contribution of the genome of the embryonic stem cells is detected in at least one tissue type of the chimeric chicken by expression of the transgene. ~~progeny having a stably integrated transgene~~

22-25 (Cancelled)

26. (Currently Amended) The chimeric chicken of claim 21 wherein the contribution of the embryonic stem cells is detected in extra-embryonic tissue ~~size of the transgene is greater than 100 kb~~.

27. (Currently Amended) The chimeric chicken of claim 21 wherein the contribution of the embryonic stem cells ~~exogenous protein~~ is detected in somatic tissue of the chicken.

28. (Currently Amended) The chimeric chicken of claim 27 wherein the ~~exogenous protein is expressed in~~ somatic tissue is endodermal ~~of the chicken~~.

29. (Currently Amended) The chimeric chicken of claim 27 wherein the somatic tissue ~~exogenous protein~~ is in mesodermal.

30. (Currently Amended) The chimeric chicken of claim 21 wherein the mesodermal tissue is lymphocytes of the chicken.

*attached to index view summary*



Patent  
700603.3  
(former L&L 271/123)

31-40 (Cancelled)

41. (Currently Amended) A method of creating a chimeric chicken comprising:

selecting chicken embryonic stem cells having a genome comprising a stably integrated transgene from a culture sustained for more than 60 days, ~~wherein the embryonic stem cells have a genome comprising a stably integrated transgene,~~

injecting the embryonic stem cells into a recipient embryo, and

hatching a chimeric chicken from the recipient embryo wherein a contribution of the genome of the embryonic stem cells is detected by expression of the transgene in at least one tissue type of the chimeric chicken ~~the transgene is present in somatic tissue of the chimera.~~

42. (Currently Amended) The method of claim 41 wherein the injecting step is comprised of injecting embryonic stem cells into a compromised embryo, ~~transgene encodes an exogenous protein-~~

43. (Currently Amended) The method of claim 42 wherein the embryo is compromised by gamma irradiation ~~exogenous protein encoded by the transgene is expressed in the somatic tissue of the chimera.~~

44. (Currently Amended) The method of claim ~~42~~43 wherein the embryo is compromised by mechanical removal of cells from the embryo ~~somatic tissue is mesodermal tissue.~~

45. (Currently Amended) The method of claim ~~41~~44 wherein the contribution of the embryonic stem cells is detected in extra-embryonic tissue ~~mesodermal tissue is lymphocytes of the chimera.~~

*attach mail to index new summary*

Patent  
700603.3  
(former L&L 271/123)

46. (Currently Amended) The method of claim 41 wherein the contribution of the embryonic stem cells is detected in somatic tissue ~~transgene is comprised of a promoter and an operably linked selectable marker.~~

47. (Currently Amended) The method of claim 46 wherein the somatic tissue is ectodermal ~~culture is sustained more than 60 days.~~

48. (Currently Amended) The method of claim 46 wherein the tissue is endodermal ~~further comprised of the step of breeding two of the chimeras.~~

Please add new claim 51 as follows.

51. (New) The method of claim 46 wherein the tissue is mesodermal.

52. (New) The chimeric chicken of claim 27 wherein somatic tissue is ectodermal.

*attachment to interview summary*

Patent  
700603.3  
(former L&L 271/123)

### REMARKS

#### The Section 112 Issue

Applicants have resolved the section 112 issue by reciting that the contribution of ES cell progeny to the tissue types of the chicken is accomplished by detecting transgene expression.

#### The Section 102 Rejection over Pain et al.

With regard to claims 21, 26-30, 52, Pain et al do not disclose a stably integrated transgene in the ES cells used to create the chimeras. Moreover, as noted in the specification, the duration of culture is a critical parameter for ES cells and their practical use in avian transgenesis. The longest period achieved by Pain et al. was 19 days, and no demonstration of transgene or of a clonally derived ES cell was made. Accordingly, Pain et al. could not possibly disclose a transgene passed to a chimera through an ES cell and Pain et al. cannot anticipate the present claims under 35 U.S.C. § 102.

With respect to claims 41-48, 51, these method claims require the step of selecting cells from a culture maintained for more than 60 days. A careful reading of Pain et al. shows that the maximum duration of the ES cell population in culture actually used to create chimeras was 19 days. The ability to extend the culture beyond 60 days and maintain pluripotency is critical because this time frame permits both the introduction of genetic modifications through stable integration and selection of a transgene, and permits the hatching of a population of like chimeras.

*attach ment to interview summary*

Patent  
700603.3  
(former L&L 271/123)

Applicants submit that the present claims are in condition for allowance and requests such action accordingly. If an interview would facilitate examination of this application, the Examiner is invited to contact the undersigned at 949/567-6700 X 7740.

The Commissioner is authorized to charge Orrick, Herrington & Sutcliffe's Deposit Account No. 150665 in the amount of \$55.00 for a one month extension fee and for any fees that may have been overlooked and to credit any overpayments to said Deposit Account No. 150665.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

Dated: March 22, 2004

By: 

Kurt T. Mulville  
Reg. No. 37,194

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